K033176 1 of 1

JAN 2 1 2004

510(K) Summary

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	September 30, 2003
Device Trade Name:	TriStar Aesthetic Workstation
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	VLS-Star and PhotoGenica YAG lasers
Device Description:	The TriStar laser is a combination of two laser devices; one pulse dye laser and the other Nd:YAG laser. They are housed in the same box with two separate laser energy delivery fibers. Laser activation is by foot switch. Overall weight of the laser is 25 Kg, and the size is 180x62x42 cm (HxWxD). Electrical requirement is 110 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	The TriStar laser is indicated for treatment of vascular lesions, pigmentated lesions, tattoos, wrinkles and hair removal.
Comparison:	The TriStar laser is substantially equivalent to the predicated devices. They have the same principle of operation, the same wavelength and essentially the same power range as the predicate devices for the same indications for uses.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The TriStar Aesthetic Workstation laser is another safe and effective device for the intended applications.
Additional Information:	none

Name of Manufacturer: Cynosure Inc.
Laser Model Name and Number: Tristar Aesthetic Workstation Laser

Laser Type: (Circle all that apply)
Alexandrite, Argon, CO2, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other _____

Indications in this application:

At 1064nm the laser is indicated for a variety of uses including coagulation and hemostasis of vascular lesions, treatment of wrinkles, long term hair removal. At 1320nm the laser is indicated for use in general surgery and dermatology for coagulation and hemostasis of soft tissue and for the treatment of fine lines and wrinkles. (Please see Indications for Use Statement for more detailed list)
At 585-600 nm the laser is indicated for benign vascular and vascular dependent lesions removal.

FDA Document Control Number: K033176

FDA Product Code: 79GEX

Reviewer Computer Initials: CYH

Date of Clearance Letter: 01/16/04

Basis of Approval: (Circle all that apply)
Predicate Device (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser:
Operation Modes: (Circle all that apply)
CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other _____

Wavelength in Nanometers: 585-600nm, 1064 nm, 1320nm

Power/Energy Range (Watts/Joules): max 60 J/cm^2

Pulse Width: 0-40 ms

Repitition Rate: 1-3 Hz

Delivery System: Fiber optic cables
Comments:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

Mr. George Cho
Senior Vice President of Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824-4145

Re: K033176
Trade/Device Name: TriStar Aesthetic Workstation Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 30, 2004
Received: December 29, 2004

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033176

Device Name: TriStar Aesthetic Workstation Laser

Indications For Use:

585nm – 600nm: The TriStar Aesthetic Workstation laser is indicated for benign vascular and vascular dependent lesions removal.

1064nm: The TriStar laser is intended for the coagulation and hemostasis of benign vascular leasions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus laske, leg veins, spider veins and poikiloderma of civatte and treatment of benign cutaneous lesions such as but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the removal of unwanted hair, for the stable long tern, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of psuedofolliculitis barbae (PFB).

1320 nm: The TriStar laser is indicated for use in gental surgery and dermatology for the incision, excision, ablation, vaporization, coagulation and hemostasis of soft tissue. It is also indicated for the treatment of periorbital and perioral wrinkles. It is also indicated for the treatment of fine lines and wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) K033176

Prescription Use ✓ OR Over-The-Counter Use_____

(Optional Format 1-2-96)